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10/591,432	09/01/2006	Claus Frohberg	65084.000022	1423
21967	7590	02/27/2009		
HUNTON & WILLIAMS LLP INTELLECTUAL PROPERTY DEPARTMENT 1900 K STREET, N.W. SUITE 1200 WASHINGTON, DC 20006-1109			EXAMINER	
			PAGE, BRENT T	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,432	Applicant(s) FROHBERG ET AL.
	Examiner BRENT PAGE	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

Status

- 1) Responsive to communication(s) filed on 01 September 2006.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-24,26-28,30-32 and 34-41 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) 34-38 and 41 is/are allowed.
 6) Claim(s) 1-24,26-28,30-32, and 39-40 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 01 September 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No./Mail Date _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-548) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No./Mail Date <u>09/2006, 11/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-24, 26-28, 30-32 and 34-41 are pending and examined herein on the merits.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. There are 11 embedded hyperlinks in the specification, 1 in paragraph 37, 3 in paragraph 98, 2 in paragraph 323, 3 in paragraph 359 and 1 in paragraph 435. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40 recites transforming a plant cell using a "composition" according to claim 34. The specification does not define composition, and it is unclear what the plant cell is being transformed with. The metes and bounds of the claim can not be interpreted and therefore claim 40 can not be examined with respect to the prior art.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 39 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are broadly drawn to a composition comprising a nucleic acid coding an OK1 protein and a nucleic acid sequence coding an R1 protein. However, plants comprise endogenous DNA encoding these proteins, and therefore naturally occurring plants and compositions therefrom read on the claim limitations. Accordingly, the claims are drawn to a product of nature, which is non-statutory subject matter.

See Diamond v. Chakrabarty, 447 U.S. 303 (1980), Funk Bros. Seed Co. V. Kalo Inoculant Co., 233 U.S. 127 (1948), and American Fruit Growers v. Brogden Co., 283 U.S. 2 (1931).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4, 6-17, 19-24 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Frohberg (US Patent 6521816, published February 18, 2003).

The claims are drawn to a genetically modified plant comprising any genetic modification comprising the introduction of any foreign nucleic acid molecule wherein the activity of at least OK1 protein and at least one R1 protein are increased in comparison with plants that are not genetically modified, a method of manufacturing the above genetically modified plant, and a method of manufacturing a modified starch comprising extracting starch from the above plants wherein the starch is modified with a changed ratio of C-3 phosphate to C-6 phosphate, wherein at least one foreign nucleic acid molecule encodes an R1 protein, harvestable plant part and propagation materials therefrom.

Frohberg teaches a foreign nucleic acid molecule encoding an R1 protein from rice (claim 1-2) transformed into a plant cell where the activity of R1 is increased (claims 4-6), a transformed wheat or maize plant transformed with said nucleic acid molecule (claims 7-8), a process for producing the plant (claim 9) and a process for producing a modified starch (claims 10 and 13), propagation materials (claim 11) and harvestable parts (approximately paragraph 50 of the specification stating "Preferably, such a process furthermore comprises the steps of cultivating plants according to the invention and harvesting the cultivated plants and/or starch storing parts of these plants")

therefrom and modified starch (see last column under Detailed Description of invention where it says "Moreover, the modified starch obtained from plants cells of the invention may be subjected to further chemical modification...) as well as the regeneration of said transgenic plants (see column 12 lines 60-67, for example). The increase of OK1 activity is inherent since R1 directly provides its substrate in the form of p-starch, and the changed ratio of C-3 phosphate to C-6 phosphate is also an inherent property of the increased activity of the R1 protein. Although derived starch is suggested by Frohberg and well-known in the art, the method steps of deriving a starch from the modified starch taught by Frohberg is not explicitly taught by Frohberg.

Claims 1-2, 4, 6-17, 19-24, 26, 30-31 rejected under 35 U.S.C. 102(e) as being anticipated by Schewe et al (US Patent 6734340, filed October 19, 2001).

The claims are drawn to the above and also to a modified starch therefrom, as well as to flour comprising at least one modified starch.

Schewe et al teach a genetically modified wheat cell and plant (see claims 1, 7, 10, 13 and 15) that is transformed with a foreign nucleic acid molecule encoding a potato R1 protein (see claim 1) wherein the ratio of C-3 phosphate to C-6 phosphate is changed (see claim 3), a method for producing the plant (see claim 13), a method for producing a modified starch (see claim 17) propagation materials (claim 16), harvestable parts (18th paragraph preceding the Brief Description of Figures), modified starch (see Examples 3-5) and flour comprising at least one modified starch (see Example 6). The increase of OK1 activity is inherent since R1 directly provides its substrate in the form of p-starch.

Claim 39 is rejected under 35 U.S.C. 102(b) as being anticipated by Kriz et al (US patent 6307123).

Claim 39 is broadly drawn to a composition comprising nucleic acids coding for an OK1 protein and an R1 protein.

Kriz et al teach plants which inherently comprise compositions and comprise endogenous copies encoding R1 and OK1 proteins (see claims 2, 10 and 15-19, for example). It is noted that any plant comprising endogenous copies of R1 and OK1 encoding proteins would meet the limitations of the claim since “composition” is not defined in the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4, 6-17, 19-24, 26-28, 30-32 rejected under 35 U.S.C. 103(a) as being unpatentable over Schewe et al (US Patent 6734340, filed October 19, 2001).

The claims are drawn to a genetically modified plant comprising any genetic modification comprising the introduction of any foreign nucleic acid molecule wherein the activity of at least OK1 protein and at least one R1 protein are increased in

comparison with plants that are not genetically modified, a method of manufacturing the above genetically modified plant, and a method of manufacturing a modified starch comprising extracting starch from the above plants wherein the starch is modified with a changed ratio of C-3 phosphate to C-6 phosphate, wherein at least one foreign nucleic acid molecule encodes an R1 protein, harvestable plant part, propagation materials a modified starch therefrom, flour comprising at least one modified starch, and a method of manufacturing said flour.

Schewe et al teach a genetically modified wheat cell and plant (see claims 1, 7, 10, 13 and 15) that is transformed with a foreign nucleic acid molecule encoding a potato R1 protein (see claim 1) wherein the ratio of C-3 phosphate to C-6 phosphate is changed (see claim 3), a method for producing the plant (see claim 13), a method for producing a modified starch (see claim 17) propagation materials (claim 16), harvestable parts (18th paragraph preceding the Brief Description of Figures), modified starch (see Examples 3-5) and flour comprising at least one modified starch (see Example 6). The increase of OK1 activity is inherent since R1 directly provides its substrate in the form of p-starch.

Schewe et al do not specifically teach the milling of plant parts to manufacture the starch and flour therefrom. However, Schewe discloses that "Methods of producing wheat flour from wheat grains are known to one skilled in the art" (see 12th paragraph preceding Brief Description of the Figures), and the milling of wheat grain and extraction of starch for flour are well-known method steps in the art and would be obvious to one of ordinary skill in the art for obtaining flour from the wheat grain. Schewe et al also do

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not teach the isolation of "derived" starch, however, since Schewe et al do describe methods of extracting the starch, methods of deriving the starch are well-known in the art and would have been obvious steps in preparing the starch for industrial uses as suggested by Schewe et al in the 10th paragraph under "Field of Invention".

Given the state of the art and the disclosure by Schewe et al, it would have been obvious to one ordinary skill in the art to manufacture the flour taught by Schewe et al, from genetically modified wheat plants taught by Schewe et al, using standard practice in the art for manufacturing the flour as suggested by Schewe et al.

Claims 1-2, 4, 6-17, 19-24 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frohberg (US Patent 6521816, published February 18, 2003).

The claims are drawn to a genetically modified plant comprising any genetic modification comprising the introduction of any foreign nucleic acid molecule wherein the activity of at least OK1 protein and at least one R1 protein are increased in comparison with plants that are not genetically modified, a method of manufacturing the above genetically modified plant, and a method of manufacturing a modified starch comprising extracting starch from the above plants wherein the starch is modified with a changed ratio of C-3 phosphate to C-6 phosphate, wherein at least one foreign nucleic acid molecule encodes an R1 protein, harvestable plant part, propagation materials a modified starch therefrom and a method of manufacturing a derived starch and derived starch therefrom.

Frohberg teaches a foreign nucleic acid molecule encoding an R1 protein from rice (claim 1-2) transformed into a plant cell where the activity of R1 is increased (claims 4-6), a transformed wheat or maize plant transformed with said nucleic acid molecule (claims 7-8), a process for producing the plant (claim 9) and a process for producing a modified starch (claims 10 and 13), propagation materials (claim 11) and harvestable parts (approximately paragraph 50 of the specification stating "Preferably, such a process furthermore comprises the steps of cultivating plants according to the invention and harvesting the cultivated plants and/or starch storing parts of these plants") therefrom. The increase of OK1 activity is inherent since R1 directly provides its substrate in the form of p-starch, and the changed ratio of C-3 phosphate to C-6 phosphate is also an inherent property of the increased activity of the R1 protein. Frohberg also teaches using the modified starch from the invention (see the 8 paragraphs preceding the Examples under non-foodstuffs) and disclose several instances of "products derived from starch" which would include derived starch, particularly as the instant application defines derived starches to include "starch graft polymers" (see paragraph 226 of instant application) and Frohberg specifically mentions starch graft polymers as a derived product (see end of paragraph (b) under Use in Non-foodstuffs).

Given the state of the art, the instant specification and the disclosure by Frohberg, it would have been obvious to one of ordinary skill in the art to obtain derived starch from the starch taught by Frohberg as suggested by Frohberg, and one would have been motivated to obtain the derived starch based on the statement by Frohberg.

(see the 14th paragraph preceding the Examples) wherein Frohberg discloses "Due to its properties the starch obtainable from the plant cells or from the plants of the invention or obtainable by the processes of the invention is not only suitable for the specific purposes already mentioned herein, but also for various industrial uses".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 4, 6, 12-13, 15-17, 19 and 23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-11 of U.S. Patent No. 6521816. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of US patent 6521816 are drawn

to a plant cell transformed with a nucleic acid encoding an R1 protein wherein the amount of R1 is increased which would inherently lead to an increase in the activity of OK1 as discussed above, and a method of producing a genetically modified plant and a method for producing a modified starch. The claims of US patent are 6521816 are drawn to specific SEQ ID NOs for the nucleic acid and are therefore narrower in scope than the instant claims.

Claims 1-3, and 7-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10/591428. Although the conflicting claims are not identical, they are not patentably distinct from each other because if proven to be enabled, the transformation of a plant with an OK1 protein encoding nucleic acid as claimed in claim 3 of the instant application would be indistinguishable from the transformation of a plant with an OK1 protein encoding nucleic acid in claim 3 of the copending Application. Should the property of increasing the activity of an R1 protein be found to be enabled from the transformation of a plant with OK1 only, the rejected claims above would all be indistinguishable from claims 1-12 of the copending application because the increased R1 activity would be an inherent property of OK1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 7-12, and 23-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3,

5-8, 21 and 25-27 of copending Application No. 10/591540. Although the conflicting claims are not identical, they are not patentably distinct from each other because if proven to be enabled, the transformation of a plant with an OK1 protein encoding nucleic acid as claimed in claim 3 of the instant application would be indistinguishable from the transformation of a plant with an OK1 protein encoding nucleic acid in claim 3 of the copending Application. Should the property of increasing the activity of an R1 protein be found to be enabled from the transformation of a plant with OK1 only, claims 1-3, 7-12, and 23-28 above would all be indistinguishable from claims 1-3, 5-8, 21 and 25-27 of the copending application because the increased R1 activity would be an inherent property of OK1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 34-38 and 41 appear to be allowable and are free of the art given the failure of the prior art to teach or reasonably suggest a recombinant nucleic acid molecule comprising a nucleic acid molecule encoding an OK1 protein and a nucleic acid molecule coding an R1 protein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page
/Anne Marie Grunberg/
Supervisory Patent Examiner, Art Unit 1638